In the Supreme Court of the United States

OCTOBER TERM, 1975

NO. 74-1594

DIAPULSE CORPORATION OF AMERICA, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 40-42) is reported at 514 F.2d 1097. The memorandum opinion and order of the district court (Pet. App. 63-98) is unreported.

JURISDICTION

The judgment of the court of appeals (Pet. App. 43) was entered on March 21, 1975. The petition for a writ of certiorari was filed on June 18, 1975. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTION PRESENTED

Whether, after the entry of a permanent injunction of the Federal Food, Drug, and Cosmetic Act, the commerce of certain devices that were misbranded in violation of the Federal Food, Drug, and Cosmetic Act, the district court properly modified its injunction to bar petitioner from introducing substantially identical devices.

STATEMENT

Petitioner is the manufacturer, promoter and distributor of a device known as the Diapulse. The device resembles a conventional medical diathermy (deep heat) unit but relies upon short bursts of electromagnetic energy for its alleged therapeutic function. The machine has been promoted for its electromagnetic effect; although some heat is produced, it is too insignificant to be therapeutic (Pet. App. 65-69). In 1965 the government instituted a libel against a "Diapulse" machine pursuant to 21 U.S.C. 334, one of the enforcement provisions of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1044, as amended ("the Act"). The government alleged that the machine was misbranded within the meaning of 21 U.S.C. 352(a) by reason of numerous false or misleading claims that the machine had therapeutic value. The case was tried before a jury, which found 49 instances of false or misleading claims. The district court entered judgment condemning the machine[1] and in January 1968 the court of appeals affirmed the judgment of condemnation. 389 F.2d 612, certiorari denied, 392 U.S. 907.

Although petitioner had been given the opportunity to redeem its condemned device by bringing its labeling into compliance with the Act, it never did so, and continued marketing the Diapulse with claims found to be false or misleading in the condemnation proceeding. Consequently, in April 1968 the government brought an action in the United States District Court for the Eastern District of New York to enjoin distribution of the device. The court, after hearing evidence, issued a preliminary injunction barring the mislabeled distribution of

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[1] *United States* v. *Diapulse Manufacturing Corp.*, 269 F. Supp. 162 (D. Conn.).

the device. The court of appeals affirmed, summarizing the evidence as follows [457 F.2d 25, 29; Pet. App. 190]:

> The device had been found to be generally misbranded, in violation of the statute, and in addition, a jury of laymen had found 49 specific claims to be false or misleading. Yet the company continued its brazen advertising scheme, failing to inform its buyers and lessors of the litigation or of the dispute in medical circles about the machine's efficacy. It did not prove the machine's effectiveness or relabel it to the FDA's satisfaction. The company's persistence in marketing the device makes it highly likely that the prohibited activity will cease only on the issuance of a blanket prohibition on shipment.

The district court subsequently issued a permanent injunction which, *inter alia*, prohibited petitioner from introducing into interstate commerce "in whole or in part, assembled or unassembled" (Pet. App. 59) any Diapulse device without first obtaining the approval of the Food and Drug Administration in regard to its labeling (*id.* at 58-62). Paragraph VI of that injunction (*id.* at 62) provided: "The Court retains jurisdiction of this case for the purpose of enforcing or modifying this Permanent Injunction, and for the purpose of granting such additional relief at the instance of any of the parties as may hereafter appear necessary or appropriate." The court of appeals affirmed without opinion. 485 F.2d 677.

Petitioner then assembled a "modification kit" designed to "convert" some Diapulse devices into what it described as "P/EmF" devices, and shipped such kits in interstate commerce (Pet. App. 63-64). The government instituted contempt proceedings, alleging that petitioner

had violated the permanent injunction entered July 18, 1972. The district court found that the shipment of the kits "constituted evasion * * * of the strictures of the permanent injunction and its purpose," but nonetheless concluded that "the shipments of the kits were not of themselves shown to constitute criminal contempts that could be given to the jury * * * *" (*id.* at 92). The court declared that "the defendants are entitled to a clear command and the government to a rigorous order so that there cannot be any evasion" and that the injunction "should be elaborated and refined so that Section III of the decree will have its intended effect" (*id.* at 95). The court proceeded to outline necessary changes (*id.* at 96-97). After further hearings the court entered a modified decree (*id.* at 44-62), which essentially prohibits the marketing of the "P/EmF" devices or any other variation of the Diapulse machine that does not produce sufficient heat to be a legitimate diathermy machine unless the device's labeling has been approved by the F.D.A.

ARGUMENT

1. Petitioner contends that the district court was without power to enter a more specific permanent injunction notwithstanding the provision of the original decree expressly retaining jurisdiction to modify the decree, because the Federal Rules of Civil Procedure do not expressly authorize such an amendment. Petitioner asks this Court to grant its petition to determine whether a court has "inherent power to supersede an affirmed final judgment with a more drastic one" (Pet. 16).

This Court, however, has confronted that question on several occasions before and after the adoption of the Federal Rules of Civil Procedure and has repeatedly

held that courts do possess inherent power to modify equity decrees such as the injunction here. In *United States* v. *Swift & Co.*, 286 U.S. 106, 114, the Court noted that the district court had expressly retained power to modify the decree and added, "If the reservation had been omitted, power there still would be by force of principles inherent in the jurisdiction of the chancery. A continuing decree of injunction directed to events to come is subject always to adaption as events may shape the need."

In *Swift* the defendants had sought modification of the injunction, but the Court has applied the same principles to affirm modifications sought by the government as plaintiff. Thus, in *Chrysler Corp.* v. *United States*, 316 U.S. 556, 562, the Court held that the test to be applied in considering such requests for modification "is whether the change served to effectuate or to thwart the basic purpose of the original consent decree." See also *Hughes* v. *United States*, 342 U.S. 353, 357. Moreover, in *United States* v. *United Shoe Corp.*, 391 U.S. 244, 251, the Court held that a district court had erred in declining to modify a decree to grant more drastic relief when experience had demonstrated that the original decree was not adequate to accomplish its purpose. The Court stated that the lower court's power to do this is clear" (*ibid.*).

Although *Swift*, *Chrysler*, *Hughes* and *United Shoe Corp.* are antitrust cases, the language of those opinions clearly demonstrates that the modification power is an inherent feature of equity jurisdiction and is not unique to antitrust cases. See Note, *Developments in the Law—Injunctions*, 78 Harv. L. Rev. 994, 1082 (1965). Moreover, the Federal Food, Drug, and Cosmetic Act, like

the antitrust laws, expresses a fundamental national policy. See *United States* v. *Dotterweich*, 320 U.S. 277; *United States* v. *Park*, No. 74-215, decided June 9, 1975. Section 302 of the Act, 21 U.S.C. 332, broadly empowers courts "to restrain violations" of that Act. The courts below thus properly concluded that, in view of petitioner's previous persistent violations and its deliberate attempt to circumvent the original permanent injunction, a modified injunction was needed to protect the public against future violations.

2. Petitioner also attacks certain provisions in the revised permanent injunction. These objections are not well founded and do not present any question warranting further review by this Court.

a. Petitioner asserts (Pet. 18-20) that language in Section III(B) of the decree (Pet. App. 48) declaring that certain devices in the possession of practitioners are "deemed to be held for sale" (*ibid.*) improperly affects the rights of persons who are not parties to this case. Regardless of whether petitioner has standing to raise such a claim, Section III expressly restrains only the petitioner "and each and all of its officers, agents, servants, employees, and representatives, and those persons in active concert or participation with them who receive actual notice of this injunction"—the precise language of Rule 65(d), Fed. R. Civ. P., which defines the scope of an injunction. This provision has the effect of prohibiting petitioner and others bound by the decree, as stated above, from modifying devices already sold to practitioners in a manner contrary to the decree, as petitioner was in fact doing with its P/EmF kit.

b. Petitioner also argues that the requirement that it obtain F.D.A. clearance for its labeling "* * * is not provided for by statute or regulation" (Pet. 32), that the

Act does not sanction "the recall of devices" (*ibid.*), and that the injunction's provision authorizing the F.D.A. to conduct inspections of premises used by the petitioner for manufacture or shipment of the devices, "at reasonable times during regular working hours, within reasonable limits and in a reasonable manner" (Pet. App. 54-55), is not authorized by Section 704 of the Act, 21 U.S.C. 374, which, according to petitioner, "distinguishes 'devices' from food, drugs or cosmetics" (Pet. 32).

The requirement of F.D.A. approval of labeling was explicitly upheld by the court of appeals at an earlier stage of this litigation, 457 F.2d at 29, when it affirmed the district court's grant of a preliminary injunction and is, in any event, an appropriate remedy in the circumstances here. The provision requiring petitioner to attempt to reclaim the "P/EmF" kits it distributed (Pet. App. 45-46, 52) is, in the context of this case, an appropriate means of remedying petitioner's attempted evasion of the permanent injunction. Similarly, the inspection provision of the broadened injunction (Pet. App. 54-55) is an appropriate measure to insure against further evasion of the injunction, and its language is drawn directly from Section 704 of the Act, 21 U.S.C. 374.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the petition for a writ of certiorari should be denied.

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